UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

ELLEN MEHLMAN,

Plaintiff,

v.

ELI LILLY AND COMPANY

Defendant.

CIVIL ACTION No. 06-CV-00199 (DBH)

ELI LILLY AND COMPANY'S MOTION TO EXCLUDE THE TESTIMONY OF JOHN J. HEFFERREN

Defendant Eli Lilly and Company ("Lilly") hereby moves this Court to exclude the expert testimony of Dr. John J. Hefferren ("Dr. Hefferren"). Any testimony from Dr. Hefferren is irrelevant or unreliable and this Court should bar his testimony.

Plaintiff Ellen Mehlman ("Plaintiff") alleges injuries caused by *in utero* exposure to a DES product taken by her mother, Barbara Fleischer ("Plaintiff's Mother" or "Ms. Fleischer"). Plaintiff seeks to identify Lilly as the maker of the DES her mother took by asserting that the physical description of Lilly's pill matched that taken by her mother, and that the Lilly pill was unique. Plaintiff is correct to acknowledge that she must prove that Lilly's pill description was unique; if some of the other 80-90 companies that sold DES in 1964-1965 had similar pills, it would be just speculation to hold Lilly responsible rather than the companies that made like pills.

Plaintiff seeks to have Dr. Hefferren establish the uniqueness of Lilly's DES product. Dr. Hefferren lacks the personal knowledge and foundation to do so because, as detailed below:

(1) Dr. Hefferren relies chiefly on a 1962 publication, Identification Guide for Solid Dosage Forms, JAMA Vol. 182, No. 12, December 22, 1962 ("1962 JAMA Guide" or the "Guide"), that itself relies on work he did through 1959. That Guide, did not purport to canvas

all if not most of the drugs on the market at that time; indeed only 10 of the approximately 109 of the companies that sold DES in 1962 were referenced in that Guide.

(2) The 1962 Guide, partial as it is, cannot speak to the products on sale in 1964 and 1965.

(3) Dr. Hefferren also reviewed 250 photographs of DES pills, collected by Plaintiff's lawyer. He acknowledged at deposition that he had no knowledge of when those pills were produced. Further, he acknowledged that the photo array was incomplete and did not include all companies that sold DES.

(4) Dr. Hefferren also claims a "casual" review of publications after 1959 that listed the description of some pharmaceutical products. Those publications, however, never purported to canvas all products, but instead depicted products that had "distinctive characteristics." "Casual" review of admittedly incomplete trade publications is not a scientific basis to determine that one pill, Lilly's, was "unique."

I. USE OF THE 1962 JAMA GUIDE DOES NOT ESTABLISH THAT LILLY'S PILL IS UNIQUE.

Dr. Hefferren has no reliable foundation or personal knowledge to support his claim that Lilly's DES pill is unique and therefore his testimony should be excluded. First, Dr. Hefferren relies on the 1962 JAMA Guide to establish that Lilly's DES pill is unique. This Guide is not and was never intended to be a canvas of all drugs that were on the market, much less DES drugs that were on the market in 1964 and 1965, the time relevant to this case. Dr. Hefferren admits that the Guide contained an incomplete and voluntary sampling of drugs he received from three Chicago based companies prior to 1962. *See* Transcript of Deposition of John J. Hefferren ("Hefferren Dep.") at 99-103, 107-108 (excerpts attached as Exhibit 1 to Lynn M. Zuchowski's Affidavit in Support of Eli Lilly and Company's Motion to Strike the Testimony of John J.

Hefferren ("Zuchowski Aff."). This incomplete catalog of drugs on the market in Chicago, prior to 1962, is not at all relevant to which DES was on the market in Waltham, Massachusetts in 1964 and 1965. Dr. Hefferren also admits that this Guide was not created to identify unique pills. Rather, the Guide was designed to serve as a resource to the poison control community - to aid in the identification of unknown pills that individuals may have overdosed on. *See* Hefferren Dep. at 72 (Zuchowski Aff., Ex. 1). Dr. Hefferren has provided no basis for using the Guide for a purpose for which it was not intended. Most importantly, Dr. Hefferren has not seen all of the DES pills that were on the market in 1964 and 1965 when Plaintiff's Mother allegedly was exposed and does not have the foundation to testify that Lilly's DES pill is unique. Indeed, there is no indication that Dr. Hefferren made any effort at all to review the DES available in these years to make a determination that one product, Lilly's, was "unique." Dr. Hefferren has no basis in fact to state that Lilly's pill was unique. His testimony is therefore unreliable and irrelevant under the standards of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) and its progeny.

a. Federal Rule of Evidence 702 and *Daubert* Set the Standard for the Admissibility of Expert Testimony in this Case.

"Federal Rule of Evidence 702 'assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" *Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) (quoting *Daubert*, 509 U.S. at 597). The Rule provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court established the gatekeeping role of trial judges in evaluating the admissibility of scientific evidence pursuant to Federal Rule of Evidence 702. *Daubert,* 509 U.S. 579, 592-5 (1993). The court set forth guidelines for federal judges in their evaluation of expert testimony under a two-pronged test to determine (1) whether the theory or methodology underlying the testimony is reliable and (2) whether the expert's theory or methodology will assist the fact-finder. *See id.*

Rule 702 and *Daubert* aid judges to ensure that proffered expert testimony "is the product of reliable principles and methods." Fed. R. Evid. 702. "[T]he trial court must decide whether the proposed testimony, including the *methodology* employed by the witness in arriving at the proffered opinion, 'rests on a *reliable foundation* and is *relevant* to the facts of the case.'" *Ed Peters Jewelry Co. v. C. & J. Jewelry Co.*, 124 F.3d 252, 259-60 (1st Cir. 1997) (citing *Daubert*, 509 U.S. at 597) (expert testimony that was "internally inconsistent and unreliable" excluded) (emphasis in the original).

1. The 1962 JAMA Guide Was Never Intended to be a Comprehensive List of all Drugs on the Market.

The 1962 JAMA Guide was not intended to be a comprehensive catalog of all of the drugs on the market when the Guide was written and Dr. Hefferren has not laid any foundation to support the Guide's use outside of its intended purpose. The 1962 JAMA Guide only attempted to catalog approximately 5,000 pills, in various forms, that were sold sometime between the years 1954-1962. *See* 1962 JAMA Guide at p. 101 (Zuchowski Aff., Ex. 2), Hefferren Dep. at 71, 94-95; 99 (Zuchowski Aff., Ex. 1). Dr. Hefferren testified that there was no formal process for choosing which drugs would be included in the 1962 JAMA Guide. Rather, Dr. Hefferren testified that Sargent Drug Store, McKesson and Robins and Highland Prescription Laboratory, all of Chicago, "voluntarily" sent him samples that he ultimately included in the Guide. Hefferren Dep. at 100-101, 103-104. (Zuchowski Aff., Ex. 1). Dr. Hefferren confirmed that he made no attempt to collect every drug listed in the Drug Topics Red Book ("Red Book") and testified that he did not include descriptions for all solid dose forms of every drug on the market. Hefferren Dep. at 107-108; 132-33 (Zuchowski Aff., Ex. 1).

More importantly, with regard to DES, the 1962 JAMA Guide did not contain a comprehensive description of more than 90% of the brands of DES that were on the market when the Guide was published. In fact, Plaintiff's counsel stipulated at deposition that the 1962 JAMA Guide only included 10 of the more than 109 DES products available on the national DES market in 1962. Hefferren Dep. at 254-55 (Zuchowski Aff., Ex. 1). One simply cannot prove that a pill is unique by comparing it to an incomplete catalog of pills. Further, Dr. Hefferren has not established any foundation to support his use of data from Chicago that was collected in 1962 or before to show that Lilly's pill that was allegedly dispensed in Boston between 1964 and 1965 is unique. Dr. Hefferren has not and cannot establish any reliable foundation for using this Guide to determine whether or not Lilly's DES pill is unique and therefore the testimony must be excluded.

2. The 1962 JAMA Guide Provides Information Outside of the Relevant Time Period and Outside of the Relevant City

The 1962 JAMA Guide does not provide any information about pills that were made in 1964 and 1965 and any testimony regarding it lacks foundation and should be excluded. The 1962 JAMA Guide, which provides the basis for most, if not all of Dr. Hefferren's expert opinion, was published in 1962, at least two years before Ms. Fleischer allegedly ingested Lilly's DES. Dr. Hefferren testified that he personally performed no work to update the guide after he left the American Medical Association ("AMA") in 1959 and believed that no new drug samples were cataloged for inclusion in the guide after June, 1962. Hefferren Dep. at 77-79; 103 (Zuchowski Aff., Ex. 1). Dr. Hefferren has not laid any foundation to establish that this Guide is applicable to determining that one specific product in 1964-1965 had a unique design and any testimony regarding such is properly excluded.

Further, Dr. Hefferren testified that the drugs that he included in the Guide were based on physical samples that were "voluntarily" sent from Sargent Drug, wholesaler McKesson and Robbins and Highland Prescription Laboratory, all of Chicago. Hefferren Dep. at 100-104 (Zuchowski Aff., Ex. 1). Dr. Hefferren has laid no foundation as to how a catalog of pills from the Chicago area prior to 1962 could be useful to establish that Lilly's DES pill is unique in the National market and any related testimony must be excluded pursuant to F.R.E. 402.

3. The 1962 JAMA Guide was not Designed for Use as a Uniqueness Identifier

The 1962 JAMA Guide was created to aid in the identification of unknown pills and Dr. Hefferren has not provided sufficient facts or data to establish that it can be used to identify any pill as unique. Dr. Hefferren testified that the 1962 JAMA Guide was developed to aid pharmacists, police officers and individuals working at poison control centers in identifying unknown drugs. Hefferren Dep. at 72-73; 95-96 (Zuchowski Aff., Ex. 1). The 1962 JAMA Guide states "[t]his guide was designed to help in identifying an unknown by selecting appropriate characteristics for the unknown tablet or capsule from the series of categories of physical characteristics." 1962 JAMA Guide, p. 102 (selected excerpts attached as Ex. 2 to Zuchowski Aff.).

As described below, the 1962 JAMA Guide was not intended to serve as a catalog of every available prescription drug on the market, from which one could determine the uniqueness of a single pill. Dr. Hefferren has established no foundation for use of the 1962 JAMA Guide in this manner and any related testimony must be excluded.

II. THE 250 PHOTOGRAPHS SHOWN TO DR. HEFFERREN DO NOT REPRESENT ALL DES SELLERS, AND THOSE PHOTOS ARE NOT OF PRODUCTS SOLD IN 1964-1965.

Dr. Hefferren reviewed photographs of approximately 250 DES tablets that he received from Plaintiff's counsel. Plaintiff's counsel admits that this collection of photographs is not complete and any conclusions that Lilly's pill is unique based on comparison with this selective collection are baseless. Dr. Hefferren admits that he has not seen the universe of all available DES pills and therefore any testimony by Dr. Hefferren about his purported use photographs of DES tablets to aid in the identification of Lilly's 25 mg pill should be excluded because it lacks the required foundation under *Daubert*. The pill collection, put together by Plaintiff's counsel, represents an incomplete array of DES tablets that were manufactured and sold in an unknown time period. Demonstrated by the fact that Dr. Hefferren testified "I cannot identify a product by a picture," Dr. Hefferren's use of this pill collection is unreliable and does not support his conclusion that Lilly's pill is unique. *See* Hefferren Dep. at 157 (Zuchowski Aff., Ex. 1).

This collection of pill photographs came from Plaintiff's counsel and Plaintiff's counsel admitted that the collection does not represent the complete universe of all DES pills that were manufactured. Hefferren Dep. at 177 (Zuchowski Aff., Ex. 2) (Mr. Levine stipulated that "I didn't show [Dr. Hefferren] the world."). It is simply not possible to identify a pill as "unique" if the conclusion is based on a comparison of a pill with an incomplete catalog of photographs. The only plausible conclusion that can come from Hefferren's review of the photographs is that Lilly's pill was not one of the pills that was included in the incomplete array.

Further, Dr. Hefferren's review of undated photographs is completely irrelevant to this litigation. Dr. Hefferren testified that he has no information about when the DES tablets in the photographs were manufactured. The pills could have been made in the 1950s, 1960s, or 1970s. *See* Hefferren Dep. at 261-62 (Zuchowski Aff., Ex. 2). The pill at issue in this litigation was dispensed in 1964-1965 but, given the above, Dr. Hefferren could not say that any of the photographs represent DES products on sale in 1964-1965. It is impossible for Dr. Hefferren to reliably conclude that Lilly's pill, sold in Massachusetts in 1964-1965, is unique when that conclusion is based on a review of an incomplete collection of undated photographs. Any testimony regarding the use of this photo array must be excluded as unreliable.

III. DR. HEFFERREN HAS NO BASIS TO SAY ONLY LILLY COULD MAKE SUCH A PILL. HIS OWN EVIDENCE REFUTES THAT ASSERTION.

Dr. Hefferren cannot rely on his opinion that making a cross-scored pill is "not easy" to support a conclusion that Lilly's cross-scored pill is unique. Hefferren Dep. at 238-39 (Zuchowski Aff., Ex. 1). Dr. Hefferren is not an expert in the field of pill manufacturing and has never been published or employed in that field. *See* Curriculum Vitae of Dr. Hefferren (Zuchowski Aff., Ex. 3, Appendix 8, Ex. A). Dr. Hefferren lacks the foundation necessary to make such a conclusion and his own report identifies a number of companies listed in the 1962 JAMA Guide were able to make cross scored pills prior to 1962. Dr. Hefferren tried to support his opinion when he testified that a cross-scored pill is the most difficult pill to make and that the die (part of the machine used to make a pill) used is very sophisticated. Hefferren Dep. at 239 (Zuchowski Aff., Ex. 1). Even if this testimony is true, Dr. Hefferren still provides no basis for his conclusion that Lilly's DES pill is unique. Dr. Hefferren testified that both name and generic manufacturers need to purchase the machinery that is required to make pills, cross-scored or not. *See id.* at 235. Dr. Hefferren also testified that there would be nothing to stop a generic manufacturer from purchasing the dies and other equipment necessary to create a cross-scored pill, even if a manufacturer, such as Lilly, purchased that same machinery first. *See id.* at 238-39. Further, Dr. Hefferren's own report contains a list of manufacturers that made cross-scored pills in 1962 and before. *See* Statement of John J. Hefferren with attached exhibits ("Hefferren

Report"), Appendix 8, Exhibit C, at 1 (attached as Exhibit 3 to Zuchowski Aff.). This list of companies who made white, cross-scored pills includes, among others, Premo, Pitman Moore and Bryant -- pharmaceutical companies that are hardly household names that were obviously able to generate a "sophisticated" cross-scored pill. *See id.* Finally, Dr. Hefferren lacks the required knowledge to conclude that Lilly's pill is unique because he has not seen the total universe of cross-scored pills that were manufactured and any conclusions of uniqueness are inherently unreliable.

IV. DR. HEFFERREN'S "CASUAL OVERSIGHT" OF THE DRUG MARKET IS NOT SCIENTIFICALLY BASED AND RELATED TESTIMONY MUST BE EXCLUDED

Dr. Hefferren also relies on a "casual oversight" of the prescription market in the 1960s and 1970s to help him conclude that Lilly's pill is unique. This non-scientific review of a limited number of publications and trade magazines does not provide Dr. Hefferren with enough factual knowledge to make a uniqueness determination. After Dr. Hefferren left the AMA in 1959, he claimed to have stayed abreast of pills in the pharmaceutical market by maintaining a "casual oversight" of trade publications including the Red Book and JAMA. Hefferren Dep. at 226-28 (Zuchowski Aff., Ex. 1); Hefferren Report at 1-2 (Zuchowski Aff., Ex. 3). Dr. Hefferren testified that he reviewed of "the sort of dosage forms that were available" from approximately 1959 until 1971 by looking at the photographs and advertisements that were in these publications. Hefferren Dep. at 227-28 (Zuchowski Aff., Ex. 1). Dr. Hefferren admitted that these journals only published pictures of pills that were "clearly identifiable" or that were "distinctive and easier for people to differentiate." *Id.* at 91; Hefferren Report at 1-2 (Zuchowski Aff., Ex. 3). Any reliance on a casual review of publications that contained some of the pills on the market during the relevant time period cannot be relied on to establish that any pill is unique. Dr. Hefferren's testimony regarding this oversight must be excluded as incomplete and unreliable.

V. LILLY'S PILL DESCRIPTION IS NOT IN DISPUTE, IDENTIFICATION OF A LILLY PILL AS A LILLY PILL ADDS NOTHING TO DR. HEFFERREN'S UNIQUENESS ARGUMENT.

Dr. Hefferren's statement that a Lilly pill dispensed in Texas in 1969 matches the description here is irrelevant. *See* Hefferren Report (Zuchowski Aff., Ex. 3). There is no dispute over what Lilly's pill looked like and establishing that a Lilly pill is a Lilly pill adds nothing to Dr. Hefferren's conclusion that Lilly's pill is unique.

All of Dr. Hefferren's analyses that lead him to the conclusion that Lilly's pill is unique are based on circular logic. Dr. Hefferren must have assumed that Lilly's pill was unique in order to reach that conclusion in each of his "studies." Hefferren has not provided any evidence that Lilly's pill is unique. Rather, he relied on that assumption when he looked at the incomplete 1962 JAMA Guide, the incomplete undated photo array, and when he identified Lilly's 25 mg DES pill that was allegedly dispensed in Texas in 1969. Dr. Hefferren does not have the factual foundation to conclude that Lilly's DES is unique and his testimony should be excluded.

CONCLUSION

For the foregoing reasons, Lilly respectfully requests that the Court enter an Order precluding Dr. Hefferren from testifying as an expert at trial. Lilly submits that Plaintiff's proffer of Dr. Hefferren's testimony as an expert is unreliable and will not assist the jury in understanding the evidence, thus warranting its exclusion pursuant to Federal Rule of Evidence 702 and *Daubert*.

Respectfully submitted,

ELI LILLY AND COMPANY
By its attorneys,

/s/ James J. Dillon
James J. Dillon *(pro hac vice)*
Brian L. Henninger *(pro hac vice)*
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210-2600
(617) 832-1000

and

William J. Kayatta, Jr.
William J. Kayatta, Jr.
William P. Saxe
Pierce Atwood LLP
One Monument Square
Portland, ME 04101
(207) 791-1100

Dated: September 14, 2007